UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MJ

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/490,700	01/24/00	CONRAD	B	61130/JPW/KR

HM12/0328

John P White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York NY 10036

EXAMINER	
WELLS,M	
ART UNIT	**PAPER NUMBER**
1642	7

DATE MAILED: 03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/490,700	CONRAD ET AL.	
	Examiner	Art Unit	
	Matthew O. Wells	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-61 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a process for diagnosing a human autoimmune disease, classified in class 536, subclass 23.72, for example.

II. Claims 11-21, and 48, drawn to a human endogenous retrovirus, classified in class 435, subclass 235.1.

III. Claims 22-25, drawn to nucleic acids comprising at least one of the sequences illustrated in Figures 7A, 7B, 7C, 7D, 7E, or a nucleic acid sequence encoding the POL protein shown in Figure 7H, or a sequence exhibiting at least 90% homology with any of these sequences, or a fragment of any of these sequences, classified in class 536, subclass 23.72.

IV. Claims 26-30, and 44-47 drawn to a protein encoded by the human endogenous retrovirus, classified in class 530, subclass 300.

V. Claims 31-33, drawn to the antibody to the protein encoded by the human endogenous retrovirus, classified in class 530, subclass 388.35.

VI. Claims 34-36, drawn to a transfected cell line, classified in class 435, subclass 235.1.

VII. Claim 37, drawn to a process for identifying substances capable of binding to the protein encoded by a human endogenous retrovirus, classified in class 435, subclass 7.1.

VIII. Claims 38-40, and 43, drawn to a process for identifying substances capable of blocking SAg activity of the endogenous retrovirus, classified in class 435, subclass 7.1.

IX. Claims 41-42, drawn to a process of identifying substances capable of blocking transcription or translation of the human endogenous retroviral SAg-encoding nucleic acid sequences, classified in class 435, subclass 6.

X. Claim 49, drawn to a substance capable of binding to the retroviral protein encoded by the human endogenous retrovirus, classified in class 424, subclass 159.1.

XI. Claims 50-52, drawn to the use of a substance capable of inhibiting retroviral function, classified in class 424, subclass 159.1.

XII. Claims 53-57, drawn to a process for detecting human autoimmune disease associated with expression of human endogenous retrovirus SAg, classified in class 435, subclass 6, for example.

XIII. Claim 58, drawn to a process of detecting SAg activity, classified in class 435, subclass 70.1.

XIV. Claims 59-60, drawn to a process for isolating and characterizing a human retrovirus, classified in class 536, subclass 24.32.

XV. Claim 61, drawn to a transgenic animal, classified in class 800, subclass 13.

If Group I is elected, a further election of species is required as set forth below.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. a mRNA

b. a protein

c. an antibody

d. SAg activity

These groups are distinct as they have different structures and functions, and are detected by different means.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. The inventions are distinct, each from the other because of the following reasons:

a. The products of groups II-VI, X, and XV are unrelated. The products of these groups are structurally and functionally different.

b. The methods of groups I, VII-IX, and XI-XIV are unrelated. The methods of these groups are for different purposes and have different and distinct method steps.

c. Inventions IV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of group IV can be used in a materially different process of affinity purification or antibody purification.

d. Inventions V and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of group V can be used in a materially different process of protein purification.

e. Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the substance of group X can be used in a materially different process of protein purification.

f. Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of group IV can be used in a materially different process of diagnosing the presence of a human autoimmune disease.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew O. Wells whose telephone number is 703-308-4521. The examiner can normally be reached on M-F (7:00-4:30), every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Matthew Wells
March 23, 2001